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REGULATORY IMPACT ANALYSIS OF REGULATIONS ON MICROBIAL PRODUCTS OF BIOTECHNOLOGY

VOLUME I: TECHNICAL REPORT

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EXECUTIVE SUMMARY

This Regulatory Impact Analysis (RIA) examines the potential costs, benefits, and impacts of regulation of microbial products of biotechnology under the Toxic Substances Control Act (TSCA). The analysis is presented in eight chapters: Introduction; The Regulated Community; Benefits of the Rule; Industry Costs; Government Costs; Effects of the Rule on Innovative Activity; International Considerations; and Effects of the Rule on Small Businesses.

A. Introduction

The U.S. Environmental Protection Agency is modifying its current policy under TSCA (as set forth in its 1986 Policy Statement) regarding oversight of "new" microorganisms. Changes to the Agency's current policy include the use of section 5(h)(4) of TSCA to limit reporting for certain categories of "new" microorganisms and revised notification rules for microorganisms intended for use in research and development (R&D) activities.

The requirements contained in the provisions of the rule, which include notification, recordkeeping/documentation, and consent agreements, vary depending on the type and stage of development of a "new" microorganism intended for commercial purposes. For example, organizations manufacturing, importing, or processing "new" microorganisms that are subject to oversight and intended for use in certain commercial R&D applications involving environmental release could choose to submit a TSCA Experimental Release Application (TERA) in lieu of the notice required at the commercial level, the Microbial Commercial Activity Notice (MCAN). Notification in connection with the intended general commercial use (GCU) of a "new" microorganism, that is, use for commercial purposes other than R&D, would be via the Microbial Commercial Activities Notice (MCAN).

Like the notification formats, the various exemption mechanisms incorporated into the provisions of the rule also vary by type and stage of development of the microorganism. An example of two exemption provisions specifically for the R&D stage included in the rule are the

"contained structure" exemption and the exemption termed "TERA Exempt." The former applies in cases where microorganisms intended for use in commercial R&D are to be confined in a contained structure. In contrast, the latter applies in cases where specifically listed microorganisms intended for commercial R&D are to be used outside of contained structures.

B. The Regulated Community

The microorganisms potentially affected by the rule are those for which the corresponding chemical use would be subject to TSCA jurisdiction. By statute, TSCA regulates all chemical applications not specifically excluded in the Act. Statutorily excluded application areas include medical, food and beverage, and pesticide applications.

Although unable to quantify the exact magnitude of activity in the biotechnology industry that is subject to TSCA, the Agency believes that activities involving "new" microorganisms covered by the rule comprise a modest share of overall activity. According to one estimate, there are over 1,000 companies pursuing biotechnology activities in the U.S.; of these, however, the Agency has identified about 130 firms as being involved in commercial R&D or general commercial use of microorganisms in applications that fall under TSCA jurisdiction. EPA estimates the share of total R&D spending in biotechnology activities subject to TSCA to be roughly 7 to 13 percent.

In annual sales, the portion of the biotechnology industry active in areas subject to TSCA appears to be divided sharply between large and small firms. EPA estimates that roughly half of the companies potentially affected by the rule have sales of $40 million or more, while most of those remaining are estimated to have sales of under $10 million.

With the expanding role of universities in the field of biotechnology and the increasing number of financial relationships developing between industry and universities, it is likely that some portion of R&D conducted at universities would be subject to the rule (if the work were determined to be conducted for commercial purposes, as defined in the rule).

C. Benefits

Possible adverse impacts associated with the use of "new" microorganisms could include health effects on humans, animals, and plants, increased costs or decreased productivity in farming and other areas of the economy, and ecological impacts whose long run health or economic effects may not be immediately apparent. To avoid these potential impacts, the provisions of the rule have been designed to reduce risks associated with the introduction of "new" microorganisms into the environment.

The risk reduction potential of the rule may be realized through a number of different actions taken by both EPA and the regulated community. The mechanism used by the Agency to obtain a given industry action depends on the type of activity intended to be undertaken and on the willingness of the submitter to cooperate voluntarily.

The benefits associated with the requirements contained in the rule arise in connection with the rule's risk reduction potential. By reducing risk, social costs associated with remediation of damages to health and the environment, including costs associated with partially or totally irreversible effects, can be avoided. The rule also contributes to greater regulatory efficiency, as it is estimated that the notification rules contained in the rule will provide the public with more risk reduction per dollar expended as compared to current policy. Finally, the pace of commercialization is also expected to be enhanced, as uncertainty regarding EPA's development of regulatory requirements and public concern in connection with perceived risks of environmental introductions of "new" microorganisms would be addressed. Exemptions could also reduce regulatory burdens for whole groups of products, relative to current policy.

D. Industry Costs

Industry costs are estimated for "Year 1" and "Year 5" in this analysis. Year 1 costs represent the expected costs for regulation of biotechnology products in the early stages of oversight while Year 5 costs, estimated by projecting industry growth forward for a period of 5 years beyond the time of the rule, represent an estimate of cost impacts associated with a more mature industry. Costs are reported in incremental terms, or in terms of costs in excess of the costs associated with the current regulatory requirements.

The incremental quantified costs to industry resulting from the rule in 1987 and adjusted values for 1995 are presented in Tables ES-1a and ES-1b. As is shown in the tables, incremental costs for Year 1 are estimated to fall within the range of $894,343 to $2,239,734 in 1987 dollars and between $1,212,729 and $3,037,039 for 1995 dollars. Values in Year 5 fall within the range of $69,696 to $510,722 for 1987 and $94,508 to $562,539 for 1995. These estimates reflect only direct, quantified costs of regulation under TSCA. Because there are many costs that could not be quantified, the results should be viewed as conservative estimates of overall costs.

The first two categories on the chart depend on the number of filings received by the Agency. The first category, total reporting or submission costs, includes the costs of developing, submitting, and certifying scientific

Table ES-1a. Industry Costs Resulting from Final Rule
(1987 Dollars)

Cost Element	Average Expected Costs: Low Cost Case	Average Expected Costs: High Cost Case
Year 1		
Reporting or Submission Costs	$ -34,845	$ 70,390
Post Review Monitoring Costs	$ 142,500	$ 585,000
CBI Substantiation Costs	$ -3,776	$ -5,076
Recordkeeping Costs	$ 4,224	$ 16,940
Rule Familiarization Costs	$ 786,240	$1,572,480
Total Costs to Industry in Year 1	$ 894,343	$2,239,734
Year 5		
Reporting or Submission Costs	$ -66,960	$ -80,402
Post Review Monitoring Costs	$ 142,500	$ 585,000
CBI Substantiation Costs	$ -10,728	$ -13,632
Recordkeeping Costs	$ 4,884	$ 19,756
Rule Familiarization Costs	$ 0	$ 0
Total Quantified Costs to Industry in Year 5	$ 69,696	$ 510,722

Note: Negative costs represent cost savings of the final rule as compared to current policy.

Source: Appendix D.

Table ES-1b. Industry Costs Resulting from Final Rule
(1995 Dollars)

Cost Element	Average Expected Costs: Low Cost Case	Average Expected Costs: High Cost Case
Year 1		
Reporting or Submission Costs	$ -47,250	$ 95,449
Post Review Monitoring Costs	$ 193,230	$ 793,260
CBI Substantiation Costs	$ -5,120	$ -6.883
Recordkeeping Costs	$ 5,728	$ 22,971
Rule Familiarization Costs	$1,066,141	$2,132,282
Total Costs to Industry in Year 1	$1,212,729	$3,037,039
Year 5		
Reporting or Submission Costs	$ -90,798	$ -109,025
Post Review Monitoring Costs	$ 193,230	$ 793,260
CBI Substantiation Costs	$ -14,547	$ -18,485
Recordkeeping Costs	$ 6,623	$ 26,789
Rule Familiarization Costs	$ 0	$ 0
Total Quantified Costs to Industry in Year 5	$ 94,507	$ 692,539

Note: The Regulatory Impact Analysis of Regulations on Microbial Products of Biotechnology prepared on January 14, 1994 presented costs in terms of 1987 wage rates. These values have been revised to reflect current wage rates. Specifically, industry costs for selected regulatory options were updated based on estimated increases in labor category cost estimates between March 1987 and June 1995.

According to the Bureau of Labor Statistics Employment Cost index, the average percent rate of increase in total compensation between March 1987 and June 1995 was 35.6% (BLS 1995). This value was used to inflate values for Year 1 and 5 of the quantified industry costs of selected regulatory options in this table.

Negative costs represent cost savings of the final rule as compared to current policy.

Source: Appendix D.

and other information for EPA. The second category, total post-review monitoring costs, results from certain restrictions placed on R&D or industrial activity following Agency review of a submission. The third item, recordkeeping costs, reflects the costs of maintaining records in connection with microorganisms intended for R&D use in contained structures. Total recordkeeping costs depend on the number of research facilities involved in activities subject to the rule, as well as the number of research projects conducted. Total costs associated with CBI (or confidential business information) substantiation are also filing-dependent; whereas the final item, rule familiarization costs, reflects the one-time familiarization costs incurred by affected facilities.

Other factors may affect potential costs but were not quantified. These factors include potential delays in product marketing, product withdrawal, or product rejection (these factors are addressed in Chapter VI - Effects of the Rule on Innovative Activity). Also, some businesses may be subject to state rules, and may have already developed regulatory compliance programs for activities not regulated by current EPA policy; cost impacts in connection with this rulemaking initiative could thus be mitigated in such areas.

E. Government Costs

Costs to the U.S. Government, attributable to the review of materials submitted by the regulated community under the rule are also estimated for Year 1 and Year 5. These costs are calculated in incremental terms, or as costs resulting from the rule compared to the cost of current regulatory requirements. These costs fall into two categories: operating costs associated with subcommittee meetings of external peer review panels; and annual costs associated with the review of submission materials performed by EPA staff.

Tables ES-2a and ES-2b present incremental costs to the government for 1987 and adjusted values for 1995. As shown in the tables, total costs to the government in Year 1 were estimated to fall between $114,896 to $121,584 in 1987 dollars and between $155,799 to $164,868 for 1995 dollars. Total government savings expected in Year 5 were estimated to reach a maximum of $105,344 in 1987 dollars or $142,846 in 1995 dollars.

F. Effects of the Final Rule on Innovative Activity

As a result of the rule, members of the regulated community may find product development strategies in connection with certain products to require reassessment. Since potential impacts of this nature could influence the degree of emphasis a firm places on innovative activity, a qualitative discussion of the potential impacts the rule may have on innovation has been developed and incorporated into this analysis.

The high degree of uncertainty surrounding both the potential for commercial success of a biotechnology product in a particular market area and the regulatory costs associated with its development make it impossible to estimate innovation impacts quantitatively. Members of the regulated community themselves may find weighing the financial risk of product development against potential returns to be difficult in many cases. Potential products for which regulatory costs constitute significant portions of overall development costs may be candidates for reassessment, although firms may need to ensure that other factors are adequately considered prior to making any decisions regarding product development.

Tailoring the regulatory process to shift burdens toward those microorganisms associated with the greatest uncertainties regarding risk can minimize negative impacts on innovation. Also, it should be noted that

Table ES-2a. Total Government Costs Resulting from the Final Rule
(1987 Dollars)

Type of Cost	Year 1 Low	Year 1 High	Year 5 Low	Year 5 High
External peer review				
Final Rule	24,840	33,900	20,700	28,250
Baseline	0	0	0	0
Incremental Costs	$ 24,840	$ 33,900	$ 20,700	$ 28,250
Agency Review				
Final Rule	789,884	1,453,728	668,118	1,222062
Baseline	738,140	1,417,732	752,388	1,423,156
Incremental Costs	$ 51,744	$ 35,996	(84,270)	(201094)
Total Net Cost to EPA	$ 76,584	$ 69,896	(63,570)	(172844)
User Fees Paid to US Treasury				
Final Rule	10,000	10,000	15,000	15,000
Baseline	55,000	55,000	82,500	82,500
Incremental Costs[a]	(45,000)	(45,000)	(67,500)	(67,500)
Net Government Cost	$121,584	$114,896	3,930	(105,344)

Sources: Tables V-2, V-5, V-6, and V-7, Appendix D.

[a] User fee costs represent a net cost to the Government because the current policy would generate higher user fee revenue than the final rule.

Note: Because the relative difference for the high cost case is smaller than for the low cost case, high and low cost estimates are reversed.

Table ES-2b. Total Government Costs Resulting from the Final Rule
(1995 Dollars)

Type of Cost	Year 1 Low	Year 1 High	Year 5 Low	Year 5 High
External peer review				
Final Rule	33,683	45,968	28,069	38,307
Baseline	0	0	0	0
Incremental Costs	$ 33,683	$ 45,968	$ 28,069	$ 38,307
Agency Review				
Final Rule	1,071,083	1,971,255	905,968	1,657,116
Baseline	1,000,918	1,922,445	1,020,238	1,929,799
Incremental Costs	$ 70,165	$ 48,811	(114,270)	(272,683)
Total Net Cost to EPA	$ 103,848	$ 94,779	(86,201)	(234376)
User Fees Paid to US Treasury				
Final Rule	13,560	13,560	20,340	20,340
Baseline	74,580	74,580	111,870	111,870
Incremental Costs[a]	(61,020)	(61,020)	(91,530)	(91,530)
Net Government Cost	$164,868	$155,799	5,329	(142,846)

Sources: Tables V-2, V-5, V-6, and V-7, Appendix D.

[a] User fee costs represent a net cost to the Government because the current policy would generate higher user fee revenue than the final rule.

Note: The Regulatory Impact Analysis of Regulations on Microbial Products of Biotechnology prepared on January 14, 1994 presented costs in terms of 1987 wage rates. These values have been revised to reflect current wage rates. Specifically, government costs for selected regulatory options were updated based on estimated increases in labor category cost estimates between March 1987 and June 1995.

According to the Bureau of Labor Statistics Employment Cost index, the average percent rate of increase in total compensation between March 1987 and June 1995 was 35.6% (BLS 1995). This value was used to inflate values for Year 1 and 5 of the quantified government costs of selected regulatory options in this table.

Because the relative difference for the high cost case is smaller than for the low cost case, high and low cost estimates are reversed.

impacts on innovation are not necessarily harmful in all cases because not all innovations will be valuable enough to outweigh the costs and risks they impose. In cases where public opposition to products beneficial to society is based on misperceptions regarding risk, a regulatory review process that addresses public concerns could spur innovation.

G. International Considerations

The regulatory requirements of the rule are examined in the context of progress made in the development of regulatory initiatives in foreign countries. The foreign countries considered include European Community (EC) nations, Japan, and Canada.

A considerable amount of additional research would be required to determine fully the impacts of the rule on the international competitiveness of U.S. biotechnology firms. However, several preliminary observations have been made for this analysis. First, any moderate effects of the rule on industry cost -- positive or negative -- could be overwhelmed by other technical, economic and legal forces affecting international competitiveness.

Second, while it was not possible to project impacts of the rule on U.S. research and innovation, in theory, any negative impacts on innovation at home could also affect the U.S. international position. Any such negative impacts might be partly mitigated by gains in other biotechnology fields (e.g., medical or animal health), if company or university resources were diverted away from TSCA applications and into other areas of biotechnology research. Conversely, any encouragement of innovation due to the rule would tend to help the U.S. competitive position.

Third, it is difficult to draw precise conclusions concerning the relative stringency of various national regulations, both because the regulatory frameworks in leading biotechnology countries are in a state of transition and because previous regulatory language did not fully capture the actual stringency of requirements when put into practice. Actual requirements may depend, to some extent, on local social, economic, and political factors as well as the actual regulatory language and scientific considerations. Overall, the similarities among stated national regulatory approaches examined for this RIA were more striking than the differences. Truly significant

differences may not become apparent until there have been several years of experience with the various regulatory schemes.

H. Effects of the Final Rule on Small Businesses

For the purposes of this analysis, EPA defines a small business to be a company with annual sales of $40 million or less. Based on this definition, EPA found in its Initial Regulatory Flexibility Analysis (IRFA) that a substantial portion of the regulated community could be classified as small businesses.

Although data were not available that would allow standard criteria developed by the Agency to assess the magnitude of small business impacts to be employed, the Agency's finding of a substantial portion of small businesses in the regulated community prompted EPA to propose flexibility options to provide relief to small businesses potentially affected by the rule.

In developing flexibility options, two major issues were considered. First, the flexibility options should not result in an unreasonable risk. Second, regulatory burden for small businesses should be reduced.

Therefore, one proposed flexibility option would reduce up-front CBI substantiation requirements for small businesses. This alternative would reduce compliance costs, since some CBI claims may never require substantiation (typically, substantiation would be required at the time of a Freedom of Information Act request), while at the same time having little effect on level of risk. A second alternative would be to eliminate the $100 notification filing fee charged to small businesses. In the preamble to the rule, EPA requested comment on its IRFA.

While comments specifically addressing the Agency's Initial Regulatory Flexibility Analysis (IRFA) were not received, comments were submitted indicating concern for impacts on products of low-value or limited use. Comments were also received on the Agency's proposed alternatives for substantiation of confidential business information (CBI) claims in connection with TERA submissions.

With regard to comments regarding smaller-scale products development, EPA finds that, because smaller scale projects of limited use would most likely be exempt or involve a relatively

limited set of use and exposure scenarios, burdens due to regulatory review would be expected to be minimal; thus, the impacts of greatest concern to smaller institutions or organizations could be frequently mitigated. In considering comments regarding CBI substantiation, EPA has decided not to require up-front CBI substantiation in connection with TERA submissions. The Agency considered reducing up-front CBI substantiation requirements for small businesses submitting TERAs in its IRFA; thus, EPA views the CBI substantiation requirements contained in the final rule as providing maximum flexibility to small businesses (or any business) conducting R&D.